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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/711,476 11/13/00 CASKEY

C 2875.1001-00

EXAMINER

HM12/1010

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FREDMAN, J	
ART UNIT	PAPER NUMBER

1655

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/711,476

Applicant(s)
Caskey

Examiner
Jeffrey Fredman

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-53 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/564,100.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Sequence Rules

1. This application complies with the Sequence Rules and the sequences were entered by the Scientific and Technical Information Center.

Double Patenting

2. Claims 22-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,153,379. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are a species of the current claim genus and therefore the narrower patented claims necessarily anticipate the broader genus claims.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 42-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Goelet et al (U.S. Patent 6,004,744).

Goelet teaches a method of analyzing the sequence of a polynucleotide (abstract) comprising the steps: a) contacting a polynucleotide of interest with a population of single stranded primers wherein said single stranded primers comprise an array of a set of primers wherein the oligonucleotides differ by at least one base at the 3' end (see figures 9-11 and column 23) and where each primer has a known sequence and is attached to a solid support at a known location to form the array and where at least one primer hybridized to the polynucleotide of interest immediately adjacent to one or more nucleotides to be identified to generate template single stranded primer complexes (column 23 and figures 9-11), b) subjecting the primer complexes to a single base extension reaction using a polymerase and four nucleotides corresponding to the four bases to extend the annealed primers by the addition of a terminating nucleotide, generating an extended primer (column 23 and figures 9-11), c) identifying each terminating nucleotide that has been added to each extended primer (column 23 and figures 9-11).

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Goelet teaches the use of four dideoxynucleotide bases which are differently labeled with different fluorescent labels (column 24, lines 52-67). Goelet teaches detection using both strands, the sense and antisense, to analyze the complimentary polynucleotide of interest (column 23, lines 52-64). Goelet teaches the use of primers which are 21 nucleotides (such as SEQ ID Nos: 13-16).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 22-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goelet et al (U.S. Patent 6,004,744) in view of Rust et al (U.S. Patent 5,605,794).

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Goelet teaches a method of analyzing the sequence of a polynucleotide (abstract) comprising the steps: a) contacting a polynucleotide of interest with a population of single stranded primers wherein said population of single stranded primers comprises at least two different oligonucleotides wherein said oligonucleotides have known sequences, such that at least two oligonucleotides hybridize to the polynucleotide of interest immediately adjacent to one or more nucleotides to be identified to generate template single stranded primer complexes (column 20, example 4 and columns 9-11), b) subjecting the primer complexes to a single base extension reaction using a polymerase and four nucleotides corresponding to the four bases to extend the annealed primers by the addition of a terminating nucleotide, generating an extended primer (column 20, example 4 and columns 9-11), c) separating said extended primers from each other using gel electrophoresis (column 21, example 4 and columns 9-11), d) identifying each terminating nucleotide that has been added to each extended primer (column 21, example 4, see figure 4, also columns 9-11). Goelet teaches the use of four dideoxynucleotide bases which are differently labeled with different fluorescent labels (column 24, lines 52-67). Goelet teaches detection using both strands, the sense and antisense, to analyze the complimentary polynucleotide of interest (column 23, lines 52-64). Goelet teaches the use of primers which are 21 nucleotides (such as SEQ ID Nos: 13-16). Goelet teaches the use of spectrophotometric detection (column 25, lines 10-14) which includes devices that use CCD or PMT detection processes well known in the art at the time of invention.

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While Goelet uses a variety of oligonucleotides of different lengths, Goelet does not expressly teach the use of primers of different lengths.

Rust teaches that for specific detection of nucleotide extension products, "by making use of the fact that the oligonucleotides are discriminated by one more feature. Such a distinction could be, for example, the varying lengths of oligonucleotides of one set. The extension of different oligonucleotides then produced products of different length (column 11, lines 6-11)".

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method of Goelet with the use of primers of different lengths as taught by Rust, since Rust expressly motivates the use of different length primers in order to achieve specific detection of extension products (column 11, lines 4-11).
device.

Allowable Subject Matter

8. The following is a statement of reasons for the indication of allowable subject matter:
Claim 53 is free of the prior art. The claim is drawn to an embodiment in which the oligonucleotide array is regenerated by digestion of the newly added nucleotide after completion of the assay. The cited prior art of Goulet, Rust, or Cantor in the IDS, do not teach regeneration of the array by cleavage mechanisms.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman, Ph.D. whose telephone number is (703) 308-6568.

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The examiner is normally in the office between the hours of 6:30 a.m. and 4:00 p.m., and telephone calls either in the early morning or the afternoon are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655

October 5, 2001